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EXAMINER	
TSANG, C	

ART UNIT	PAPER NUMBER
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JAMES F. HALEY, JR.
FISH & NEAVE
1251 AVENUE OF THE AMERICAS
50TH FLOOR
NEW YORK, NY 10020

DATE MAILED: 05/23/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 3/15/94 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449. 2 sheets
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 3-5, 7, 10, 21 and 22 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 1, 2, 6, 8, 9, 11-20 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 3-5, 7, 10, 21 and 22 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☒ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☒ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

Claims 3-5, 7, 10, 21 and 22 are pending.

Claims 3-5, 7, 10, 21 and 22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following reason applies"

"A compound which----or an antivirally active metabolite or residue thereof" is unclear. The specification does not provide any guidance. Prodrug is generally defined as a derivative of a parent drug which is converted in vivo (by way of many different chemical processes) into active, parent drug, the choice of such derivative (i.e. the prodrug) will vary from drug to drug since the function of prodrugs is to improve the pharmokinetics of the active form (e.g. solubility, prevention of drug loss before the receptor site is reached) and thus the choice of a suitable prodrug will be a function of the molecular structure of the active form, as well as the desired intended effect. The specification provides no guidance as to what constitutes suitable prodrug(s) "a salt, ester, or salt or an ester" remains unclear. The specification does not provide any guidance.

Claims 3-5, 7, 10, 21 and 22 are rejected under 35 USC 103 and 102 over US '466. Applicant's urges that one of ordinary skill would expect the "nonnatural" nucleoside analogue to have little or no activity. It is well known in the antiviral art that any small change may significantly affect the activity. Attention is also invited to Chang et al article of record. Since compound disclosed there has four possible stereoisomers, all four of them were tested to find out which one is responsible for the activity and cytotoxicity. Thus, it is a routine for one skilled in the art to test all possible stereoisomers of an active compound.

As discussed in previous action, US '466 teaches how to prepare BCH-189 or BCH-189 analogs that are enantiomerically-enriched. The choice of the enzyme that is selective for the desired enantiomer (or selective for the undesired enantiomer, as a method of eliminating it) is within the skill of the art. The patent teaches how to prepare enantiomerically-enriched BCH-189 and analogs thereof. The figures, schemes and formulas are not required to reflect the configuration.

Rejection over US '407 remains for the reasons of record.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED

STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

A facsimile center has been established in Group 1200, room 3C10. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (7030 308-455 or 305-3592.

Any inquiry concerning this communication should be directed to Examiner Tsang at telephone number (703) 308-4715.

C Tsang

CECILIA TSANG
PRIMARY EXAMINER
GROUP 1200

TSANG:jd
May 19, 1994